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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PANI, JOHN

ART UNIT

PAPER NUMBER

3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,507	Applicant(s) CROSSMAN ET AL.	
	Examiner JOHN PANI	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “cap adapted to hold the lancet clear of said trigger-releasable latch until said cap is detached from the housing and from the lancet” of claim 10 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not disclose "wherein said cap is adapted to hold the lancet clear of said trigger-releasable latch until said cap is detached from the housing and from the lancet" of claim 10.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 10 recites "said cap is adapted to hold the lancet clear of said trigger-releasable latch until said cap is detached from the housing and from the lancet." The specification does not disclose or suggest this feature and Figures 4 and 5 contradict this feature. Specifically, note that in Fig. 4 the cap 5 is attached to the housing and the lancet and the lancet is located within and is contacting

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the notch of the trigger-releasing latch, and is thus not held "clear" of the latch.

Additionally Fig. 5 depicts the cap 5 still contacting the housing 1 and lancet 2 while the lancet is clearly contacting the flange 12 of the trigger-releasable latch, and is thus not held "clear" of the latch.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,817,603 to Turner et al. ("Turner").

7. Turner teaches:

In reference to Claim 1

A blood sampling device (see Figs. 1-5B) comprising a needle-carrying lancet (44) located within a housing (36) and having a cap (40) releasably attached to said lancet adjacent said needle (in configuration of Fig. 2, the cap and lancet are attached via the housing 36 and the needle and lancet are adjacent each other), the cap extending to project through an opening (42) at one end of the housing and having one locating member (54) fitting into one cooperating feature (42) of the outer walls of the housing, the cap being twistable to release the locating member from the cooperating

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feature and from the lancet (see col. 6 lines 1-5, by detaching **40** from **36**, it is also detached from the lancet, as the lancet is connected to the housing by spring **16**).

In reference to Claim 4

A blood sampling device according to claim 1 (see above) wherein the lancet is spring-loaded to urge the lancet in the direction towards the opening in the housing (see Figs. 2-4)

In reference to Claim 5

A blood sampling device according to claim 4 (see above) including a trigger-releasable (**54** acts as a trigger to release **44** from **48**) latch (**60**) to hold the lancet within the housing such that an exposed needle cannot project through said opening until the latch is released by the trigger (see Fig. 2 and 5A-5B).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2, 3, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner in view of US Pat. No. 3,165,220 to Haynes ("Haynes").

In reference to Claim 2

Turner teaches the device of claim 1 (see above) but does not teach that the locating member is a flange and that the cooperating feature is a groove. Turner

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teaches that the cap is attached to the housing with a frangible seal so that the user knows that the device is unused (see col. 6 lines 1-5). Haynes teaches a tamper-proof container enclosure in which the cap includes flanges (**34**) while the container includes grooves (**18**). The device includes frangible buttons/pins **28** which when broken, indicate that the original seal has been broken (see col. 1 line 60 – col. 2 line 60). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Turner by substituting a tamper-proof enclosure using flanges, grooves, and pins as taught by Haynes, for the heat-sealed frangible cap taught by Turner, because this substitution of one known tamper-proof enclosure for another would lead to the predictable result of allowing the user to know whether the device was previously used.

In reference to Claim 3

Turner in view of Haynes teaches the device of claim 2 (see above), and Haynes further teaches that there are two flanges fitting into grooves in two opposed sides of the outer walls of the housing (see Figs. 3-5).

In reference to Claims 8 and 9

Turner in view of Haynes teaches the device of claims 2 and 3 (see above) and Turner further teaches that the lancet is spring-loaded to urge the lancet in the direction towards the opening in the housing (see Figs. 2-4).

Response to Arguments

10. Applicant's arguments filed 5/29/2008 have been fully considered but they are not persuasive. In reference to Applicant's assertion that Turner does not teach that "the cap is releasably attached to said lancet adjacent said needle" or that "twisting the cap both detaches the cap from the housing and also from the lancet" the Examiner respectfully disagrees for the reasons stated above. In reference to Applicant's assertion that there is no suggestion of interaction between the cap and the lancet, the Examiner notes that in the configuration of Fig. 2 all the components of the device are attached together. In reference to Applicant's assertion that there is no disclosure of an arrangement in which the cap extends between the lancet and the exterior of the lancet housing and is detachably secured to both the housing and the lancet, the Examiner notes that this language is not contained in the claim.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 8/20/08

/Max Hindenburg/

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Supervisory Patent Examiner, Art Unit 3736